



BENTLEY Pharmaceuticals Inc.
65 Lafayette Road, 3rd Floor
North Hampton,
NH 03862-2403
USA

Saint Cloud, June 8th, 2001

For the attention of Mr James R. MURPHY

Dear Sir,

Further to our discussion of the beginning of year 2001, please find attached a draft of agreement aiming at regularizing the relationship between Ethypharm and Belmac.

In the course of the past weeks, it seemed that the relations between heads of our companies (industrial, legal etc..) became strained. We deeply regret this situation and hope that everyone will understand that we wish to maintain long term and good relationship with your group and that we do not intend to reach a situation of conflict which, in our opinion, would damage both companies and which, in any case, is not appropriate.

This is the reason why I propose that you and me alone, or if necessary, assisted by one of our lawyers, discuss this draft of agreement.

If you agree, we could meet, preferably in Paris, between the 3rd and the 6th of July 2001.

I look forward to hearing from you on this subject,

Yours Sincerely,

Gérard LEDUC
General Manager

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EP 002011

A-295

6947-EX00400188

TECHNOLOGY LICENCE
AND
MANUFACTURING AGREEMENT

BETWEEN THE UNDERSIGNED :

ETHYPHARM SA - with corporate domicile at Marques de la Ensenada, 16 28004
MADRID -- SPAIN

A company belonging to **ETHYPHARM S.A.** 21 rue Saint Matthieu 78550
HOUDAN - France

Hereinafter called **ETHYPHARM**

Represented by its President : Mr Patrice DEBREGEAS

OF THE ONE PART,

AND :

LABORATORIOS BELMAC S.A. with corporate domicile at C/ Montearagon 9, -
28033 MADRID - SPAIN

A company belonging to **BENTLEY Pharmaceuticals Inc.** -- 65 Lafayette Road, 3rd
Floor, North Hampton, NH 03862-2403 -- USA

Hereinafter called **BELMAC**

Represented by its Executive Director : Mr James R. MURPHY

OF THE OTHER PART

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WHEREAS :

- 1) **ETHYPHARM** is a pharmaceutical company specialized in the development, registration, manufacturing and licensing of pharmaceutical specialities and owns any and all relevant equipment, technology, know how and patents
- 2) **BELMAC** is a pharmaceutical company specialized in the development, registration, manufacturing, licensing and marketing of pharmaceutical specialities and owns any and all relevant equipment, technology, know how and patents.
- 3) **ETHYPHARM** and **BELMAC** have been cooperating since 1990 for the manufacture, control, and/or encapsulation and/or conditioning in **BELMAC**'s Premises (as defined below) of some of **ETHYPHARM**'s products, listed in the attached Annex A ("the Products" as defined below) licensed and sold by **ETHYPHARM** to **BELMAC** and **BELMAC**'s Licensees (as defined below) in Spain and to other customers of **ETHYPHARM** in Spain and outside Spain.
- 4) This cooperation, has proceeded by agreement but has never been fully confirmed through a formal Agreement signed by both parties. Nevertheless, various documents, listed in the attached Annex B, have been signed, in the past, by the Parties in order to comply with administrative requirements or to specify particular obligations of the Parties concerning this cooperation.
- 5) Throughout the term of the cooperation mentioned in point 3) herein above, **ETHYPHARM** has subcontracted the manufacturing and control of the Products to **BELMAC** for manufacture and control in the Premises. Said Premises have been initially equipped, at **ETHYPHARM**'s expenses and on the basis of Quality Assurance procedures and instructions transmitted by **ETHYPHARM** to **BELMAC**, in order to enable **BELMAC** to carry out the manufacture of **ETHYPHARM**'s products in full compliance with GMP regulations in force in Spain. As a consequence of the work performed by the Quality Assurance Department of **ETHYPHARM** in collaboration with **BELMAC** and on the basis of the relevant

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documentation established and provided by **ETHYPHARM**, the Premises have been GMP approved by the Spanish Health Authorities in September 1992. Since 1998, the Quality Assurance Department of **BELMAC** has been responsible for the good compliance of the Premises with GMP's in force in Spain and for audits performed by the Spanish Ministry of Health and Customers and Licensees in this respect.

- 6) All of the machinery and equipments set in the Premises used to manufacture and control **ETHYPHARM**'s products, except for specific equipment used in the control of the Products, have been purchased by **ETHYPHARM**.
- 7) **ETHYPHARM** has insisted that **BELMAC**'s technicians dedicated to its Products be trained locally by **ETHYPHARM** to manufacture and control of the Products at the Premises in accordance with GMP practices.
- 8) Within the framework of this continuing agreement and cooperation, **ETHYPHARM** has communicated to **BELMAC** confidential information which includes, but is not limited to, documentation relative to manufacturing processes and formulae, manufacturing and control know how, patents, quality and analytical procedures as well as other information included in the Registration Files of the Products needed by **BELMAC** to perform its manufacturing and control obligations
- 9) **ETHYPHARM** worldwide pharmaceutical operations now require it to manufacture at its own production sites in France part of its production of Products, previously entrusted over the past years to **BELMAC**.
- 10) As a consequence and to clarify the understanding between the two companies, **ETHYPHARM** and **BELMAC** have agreed to redefine the framework of their cooperation, and the conditions of use by **BELMAC** of the Technology licensed by **ETHYPHARM** to manufacture and control the Products both for **ETHYPHARM** and its Customers and for **BELMAC**'s and its Licensees.

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The parties, having regard for that stated above, with the express intention of reflecting their respective obligations in a written and binding agreement, and mutually acknowledging each party's capacity thereon, have decided to subscribe the present agreement (hereinafter, « the Agreement ») in accordance with the following clauses.

CLAUSE I -- DEFINITIONS

- 1.1. **Affiliate** shall mean any entity which controls, is controlled by or is under common control with either BELMAC or ETHYPHARM for so long as such control exists. An entity shall be regarded as in control of another entity for purposes of this definition if it owns or controls, directly or indirectly, more than fifty per cent (50%) (or with respect to an entity formed under the laws of another jurisdiction, such lesser percentage that is the maximum allowed to be owned by a foreign corporation in such jurisdiction) of the equity of the subject entity having the power to vote on or direct the officers of the entity ; except to the extent such entity is precluded by contract from exercising such control.
- 1.2. **Customers** shall mean a non-Affiliate third party whom promotion, distribution and marketing rights on the Products have been granted by ETHYPHARM in and outside the Territory
- 1.3. **"ETHYPHARM"** shall include any Affiliates involved in the activities envisaged in this Agreement.
- 1.4. **"ETHYPHARM Know How"** shall mean any proprietary information owned by ETHYPHARM or its Affiliates in relation with the Technology and the Products

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1.5. "ETHYPHARM Patent rights" shall mean all ETHYPHARM rights in and to :

- 1.5.1. Those certain patent granted and patent applications listed in Annex A hereto (ETHYPHARM Existing Applications), and ,
- 1.5.2. any foreign counterparts of the Existing Applications, and all divisions, continuations, continuations-in-part, patents of additions, and substitutions of and all patents issuing on, any of the foregoing, together with all registrations, reissues, reexaminations or extensions of any kind with respect to any of such patents, in each case to the extent the same claim and disclose subject matter disclosed in the Existing Applications.

1.6. "Licensees" shall mean a non-Affiliate third party whom promotion, distribution and marketing rights on the Omeprazol Product have been granted by BELMAC in the Territory

1.7. "Party" or "Parties" shall refer individually or collectively to BELMAC and/or ETHYPHARM

1.8. "Premises" shall mean BELMAC's factory located at Zaragoza, Poligono Malpica Calle C 4 (Spain).

1.9. "Product" or "Products" shall mean the pharmaceutical products listed in Annex A to this Agreement, including Omeprazol Product as defined below, and for which ETHYPHARM has entrusted the manufacture to BELMAC.

1.10. "Omeprazol Product" shall mean the pharmaceutical product listed in Annex A and containing Omeprazol as sole active ingredient.

1.11. BELMAC shall include any Affiliates involved in the activities envisaged in this Agreement.

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- 1.12. "Registration File" shall mean the dossier submitted to the competent authorities in order to obtain the authorization to market the Product in or outside the Territory.
- 1.13. "Technology" or "Technologies" shall mean any proprietary information owned by ETHYPHARM and its Affiliates consisting of know-how (including but not limited to secrets, patents both pending and granted), methods, processes, formulae, techniques or data necessary for the manufacture, control, sale, import or use of Products as well as any improvements made on, but not limited to, formulae and manufacturing process of the Products during the past collaboration between the Parties.
- 1.14. "Territory" shall mean Spain.

CLAUSE 2 - SUBJECT

The subject of this Agreement is to confirm the terms and conditions which will be applied, from date of signature of the present Agreement, to the business relationship under which BELMAC will be granted a licence to use the Technology, ETHYPHARM's Know How, ETHYPHARM's patent rights and equipment to manufacture and control of the Products both :

- for the sale of the Omeprazol Product, purchased exclusively from ETHYPHARM, by BELMAC and its Licensees in the Territory and,
- for the sale of the Products to ETHYPHARM's Customers in and outside the Territory.

In the event, BELMAC or its Licensees wish to export the Omeprazol Product to countries outside the Territory, BELMAC agrees to request for itself and its Licensees, on a case by case basis, prior written approval from ETHYPHARM. Such approval may be refused by ETHYPHARM, whatever the reason, including, if ETHYPHARM estimates that such extension of the Territory may alter its relationship with third parties or jeopardize or create interference with

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ETHYPHARM's intellectual property rights or for any other legal or contractual reason.

- 11) For the sake of good understanding it is hereby specified that BELMAC has been granted marketing authorizations on Omeprazol Product (as defined below) in Spain which are used directly by BELMAC and by its Licensees to market the Omeprazol Product in the Territory. Said marketing authorizations have been obtained on the basis of technical documentation originating from ETHYPHARM and subject to the present Agreement and additional work (such as stability, bioequivalence, validation) performed directly by BELMAC.

CLAUSE 3 - RIGHTS

BELMAC acknowledges that the rights granted by ETHYPHARM in the present Agreement on, but not limited to, the Technology, ETHYPHARM's Know How and ETHYPHARM's patents and equipment and their use by BELMAC are strictly limited to the cooperation, as organized in the present Agreement, between ETHYPHARM and BELMAC and BELMAC recognizes that this does not constitute a transfer of Technology and does not grant BELMAC rights to use the above mentioned elements to manufacture and to sell the Products otherwise than as specified in the present Agreement.

CLAUSE 4 - RESOURCES

4.1. Location and Premises

The manufacture and control of the Products shall take place at the Premises located at Poligono Malpica Calle C 4., in Zaragoza (Spain) which have been GMP approved in September 1992 as mentioned hereinabove. BELMAC may not change location of the Premises without prior approval of ETHYPHARM.

BELMAC shall be responsible for keeping said premises in a good sanitary, safe and steadily workable conditions during the term of this Agreement and the Quality Assurance Department of BELMAC shall continue, as organized since 1998, to achieve all modifications in the Premises in order to maintain cGMP conditions and

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minimum requirements from **ETHYPHARM** in terms of Quality Assurance procedures.

BELMAC will allow, at any time in case of specific concern in the manufacturing and control of the Product or after prior notification of two weeks in the event of regular audit, **ETHYPHARM**, its employees, representatives and Customers to have convenient and continuous access to the Premises in order to audit the conditions of manufacturing and control of the Products.

BELMAC, when audited by its Licensees, will indicate to said Licensees that the Omeprazol Product is manufactured with machinery, equipment, Technology and Know How pertaining or under licence from **ETHYPHARM**

4.2. Machinery and Equipment

It is hereby recalled, that the machinery and equipment used to manufacture the Products will remain the exclusive property of **ETHYPHARM** and may not be used by **BELMAC** otherwise than for the purpose of manufacturing and controlling the Products as provided for in this Agreement. Details relative to the investment made by **ETHYPHARM** at **BELMAC**'s Premises and the updated list of the machinery and equipments belonging to **ETHYPHARM** are indicated in Annex C to this Agreement. The Parties estimate that the present equipment and machinery shall offer sufficient capacity to enable **BELMAC** to manufacture both for **ETHYPHARM**'s customers, **BELMAC** and **BELMAC**'s licensees needs.

The present capacity of the equipment dedicated to the manufacturing of the Products is estimated at :

- 110 millions doses of Omeprazol Product per annum corresponding to eight batches of Omeprazol Product containing 1 250 000 doses each per month , (one dose being the content of one capsule manufactured in GS pans.
- 130 millions doses of Products per annum, except for Omeprazol Product, manufactured in classical pans.

The production schedule and the splitting of the above mentioned capacity between the Products ordered shall be subject to regular agreement between the production managers of each of the Parties.

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BELMAC shall be responsible for maintaining any and all machinery and equipment entrusted by ETHYPHARM in perfect working conditions for the production of the Products and shall be responsible at its own cost for daily maintenance, the compliance of regular maintenance as planned by ETHYPHARM as well as any repair of damages.. Payment of any spare parts, validation and testing of the equipment shall remain to the charge of ETHYPHARM. Moreover, BELMAC shall keep ETHYPHARM, regularly and with sufficient anticipation, informed of specific maintenance and repairs to be performed on the machinery and equipment in order not to delay production of the Products.

4.3. Documentation

All and any documentation, procedures or other information on ETHYPHARM's Know How and ETHYPHARM's Patent rights communicated or transmitted by ETHYPHARM to BELMAC or its personnel, within the framework of the cooperation described in this Agreement and needed to manufacture and control the Products, are considered as ETHYPHARM's sole property, which is acknowledged by BELMAC and is subject to confidentiality. ETHYPHARM must approve of BELMAC's use of said documentation, procedures and information may not be used by BELMAC, or its personnel for any other purpose than that described in the present Agreement.

4.4. Personnel

Personnel involved in the manufacturing and controlling of the Products shall remain employees of BELMAC. In order to check the qualification of said Personnel for the purpose of this Agreement, ETHYPHARM will have the possibility to test BELMAC's personnel enrolled to manufacture the Products and only those duly accepted by ETHYPHARM shall be considered as part of the personnel authorized to manufacture the Products.

Members of BELMAC's personnel involved in the production of the Products will be clearly identified in a separate document annexed to this Agreement and which may be modified only by written agreement between the parties. The parties agree to designate and train to the manufacture and control of the Products more technicians than actually needed in order to avoid shortage of qualified and accepted personnel.

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Moreover said members will be bound by the Confidentiality Clause subscribed by BELMAC as provided in Clause 11 hereunder and BELMAC shall be fully responsible for the compliance of the members of its personnel with said clause.

CLAUSE 5 - TERM, TERMINATION AND CONSEQUENCE OF
TERMINATION .

5.1. Term

The effectiveness of this Agreement will apply as from January 1st, 2001 and shall remain in force for an initial period of three (3) years.

Six months prior to the end of the initial period of three (3) years, the parties agree to meet in order to discuss the renewal of this Agreement.

In the event, the parties do not confirm in writing the renewal of this Agreement, this Agreement will be considered as automatically terminated.

5.2. Termination

Each party reserves the right to cancel this Agreement if the other party commits a material breach of its obligations and fails to remedy this breach within ninety (90) days of the notification of said breach by registered letter, without prejudice to any other actions that the non-defaulting party may exercise and particularly to a claim for damages.

This Agreement will be automatically terminated at the date a specified event occurs and without prejudice to the dispositions of the applicable law, namely if one of the Party is dissolved or liquidated, files or has filed against it a petition under any applicable bankruptcy or insolvency law, or makes a general assignment for the benefit of its creditors.

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5.3. Consequence of Termination

Upon termination of this Agreement, ETHYPHARM is entitled to move out, at ETHYPHARM's costs (except if termination is due to a breach of its obligation by BELMAC in which case removal will be at BELMAC's costs) any furniture, equipment, apparatus, machinery identified as belonging to ETHYPHARM, mentioned in Annex D to this Agreement.

Upon termination of this agreement for any reason, BELMAC shall cease the manufacturing of the Products and will return promptly to ETHYPHARM any and all information and data received from ETHYPHARM herein, without retaining any copy. BELMAC shall not make any further use of all information, data, know-how and the like received from ETHYPHARM either directly or indirectly and shall take all necessary step to ensure that any of its employees who have had knowledge of the confidential information or benefited from the transfer of technology shall comply with their confidentiality obligations during and after their employment contract with BELMAC.

BELMAC will have the right to deliver the Products with respect to any orders placed by ETHYPHARM or BELMAC or BELMAC's Licensees and accepted by BELMAC before the date of termination of this Agreement.

Upon termination of this Agreement, whatever the reason, ETHYPHARM shall make sure that BELMAC's needs and BELMAC's Licensees needs in Omeprazol Product shall be fulfilled from one of ETHYPHARM's production sites in order to avoid shortage of said Omeprazol Product on the market. Conditions of delivery in such event shall be those agreed upon between the parties hereinafter (clause 12.), unless otherwise mutually agreed by the Parties.

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CLAUSE 6 - MANUFACTURE OF THE PRODUCTS

BELMAC is hereby granted by ETHYPHARM the right to manufacture and control as subcontractor, the Products, both for ETHYPHARM and its customers and for BELMAC's and BELMAC's Licensees needs.

BELMAC warrants that the Products will be manufactured, controlled, encapsulated and conditioned strictly in accordance with the specifications of the registration dossier of each of the Products, the manufacturing licences obtained for each of the Products, ETHYPHARM's Know How and the Good Manufacturing Practices and all other applicable laws regulations codes of practice and standards in force in the Territory.

The above mentioned activities including the quality control involved at each production stage, will be undertaken by BELMAC's personnel trained by ETHYPHARM at BELMAC's Premises

BELMAC shall not be permitted to make any improvement or modification of the manufacturing process and specifications of the Products without the prior written consent of ETHYPHARM. Any and all improvement or modification made on the Products by BELMAC shall be considered as part of ETHYPHARM's Know How.

CLAUSE 7 - ESTIMATES AND PURCHASE COMMITMENTS

7.2. Estimates and orders

Quarterly, ETHYPHARM and BELMAC shall provide each other with forecasts of requirements for Products originating from BELMAC, its Licensees, the Customers for the succeeding twelve (12) month period. Such forecast is to be submitted at a time no later than three (3) months before the beginning of such twelve (12) month period, and is to be revised and extended on a quarterly rolling basis.

Any and all orders relative to ETHYPHARM's Products will be placed by ETHYPHARM to BELMAC ninety (90) days prior to the expected delivery date.

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BELMAC shall confirm to ETHYPHARM within a maximum of eight (8) working days the expected delivery date.

BELMAC undertakes to offer the same treatment to all orders in Products whether originating from ETHYPHARM, BELMAC itself or BELMAC's licensees.

ETHYPHARM will have the possibility to check the production schedule and delivery planning of the Products in the event BELMAC cannot meet ETHYPHARM's requirements.

ETHYPHARM shall provide BELMAC with sufficient quantity of active ingredient necessary to manufacture the orders and to cover a two(2) month stock in Products.

7.2.Delivery

ETHYPHARM's Products will be shipped by BELMAC to ETHYPHARM's designated transport agent who will ship the Products to the final Customer or Licensee in accordance with ETHYPHARM's instructions and in the name of ETHYPHARM.

BELMAC will provide ETHYPHARM with administrative services such as the preparation of all documents needed to accompany ETHYPHARM's Products during the delivery to ETHYPHARM. Any documents such as, but not limited to, the analytical certificate and batch records will be addressed to ETHYPHARM prior to any shipment. The Products will be released by BELMAC with the express authorization of ETHYPHARM.

CLAUSE 8 - QUALITY WARRANTIES

BELMAC warrants that the Products delivered hereunder shall meet the specifications of the Registration Files of the Products. BELMAC agrees to replace free of charge the Products delivered to ETHYPHARM which do not comply with the specifications, provided that ETHYPHARM notifies BELMAC of any defect within 60 days of the receipt of the Products.

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In the event of a dispute as to acceptability of a consignment of the Products and the results of analysis performed by each party, ETHYPHARM and BELMAC will name a mutually acceptable independent expert to settle the disagreement.

The results of such expertise will be binding upon the parties and the costs of such expertise will be borne by the party in default.

Should the Products comply with the specifications, then ETHYPHARM will pay for the batch initially sent free of charge by BELMAC as stipulated in the above mentioned paragraph.

Should the Products not comply with the specifications, then ETHYPHARM will return to BELMAC said Product.

BELMAC shall indemnify and hold ETHYPHARM harmless from and against any and all third party claims, losses, liabilities and expenses (including reasonable lawyers fees, and other litigation costs) arising out of or resulting from the manufacture of the Products by BELMAC or BELMAC's failure to meet any of its obligations under this Agreement.

ETHYPHARM agrees to give BELMAC prompt written notice of any claims made, for which BELMAC might be liable under the foregoing indemnification, together with the opportunity to defend, negotiate and settle such claims.

The party seeking indemnification under this Agreement shall provide the other party with all information in its possession, authority and assistance to enable the indemnifying party to carry on the defence of such suit.

BELMAC will be responsible to ETHYPHARM for all expenditure incurred by its non-compliance with the present obligations, unless this non-compliance with the present obligations, be the fault of ETHYPHARM such as by its negligence or omission of its obligations

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BELMAC will however be responsible as to the good working practice and good storage facilities in its plant and warehouses until the goods are shipped to the transport agent designated by ETHYPHARM.

CLAUSE 9 - INSURANCE AND INCIDENT

During the term of this Agreement, BELMAC shall guarantee ETHYPHARM that the Premises where ETHYPHARM's equipment, machinery and goods entrusted to BELMAC (whether raw material, semi finished or finished goods) by ETHYPHARM are kept, are covered by proper insurances against, among which but not limited to : theft, flood, fire, civil liability and any other unforeseeable events , whose occurrence and consequence may cause prejudice to ETHYPHARM.

BELMAC shall also, as subcontractor of the Products, contract a relevant and sufficient insurance policy with a company of good reputation in order to cover its civil liability in relation with default in the manufacture or control of the Products due to the non compliance of BELMAC with ETHYPHARM's instructions in relation with the use of the Technology and ETHYPHARM's Know How as well as with specifications of the Registration Files of the Products.

BELMAC shall provide ETHYPHARM, at ETHYPHARM's request, with evidence that the necessary insurance policies have been contracted and that they are maintained in force. Costs of said insurance policies shall be borne by BELMAC.

CLAUSE 10 - FORCE MAJEURE

BELMAC and ETHYPHARM shall not be considered in default of their obligations hereunder to the extent that performance of such obligations is delayed, hindered or prevented, in whole or in part, by Force Majeure. Force Majeure includes, without limitation, inclement weather, strikes, lockouts, inability to procure labor or materials or fuels due to shortages, fires, riots, incendiarism, interference by civil or military authorities, compliance with the regulations or order of any government authority, or

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the outbreak of war or insurgence, or acts of war (declared or undeclared) and any other cause which is beyond the reasonable control of either party.

Specifically excluded from this definition are those acts of Governmental authorities or any agency thereof, or judicial action which could have been avoided by compliance with such laws or regulations, publicly available and reasonably expected to be known by **BELMAC** and/or **ETHYPHARM**.

The party so prevented from complying with its obligations hereunder shall immediately notify in writing the other party thereof and such party so prevented shall exercise diligence in an endeavor to remove or overcome the cause of such inability to comply. However, neither party shall be required to settle a labor dispute against its own best judgment. Deliveries suspended or not made by reason of the present Clause shall be canceled without liability, but this Agreement shall otherwise remain unaffected.

Notwithstanding the above, if an event of Force Majeure excuses **BELMAC**'s performance such that **BELMAC** does not supply **ETHYPHARM** for a continuous period of three (3) months or more, **ETHYPHARM** shall be entitled, upon notice to **BELMAC** to suspend this Agreement and organize with **BELMAC** the manufacture and control of the Products in another cGMP approved factory of **BELMAC** or the transfer to one of **ETHYPHARM**'s production sites of the pending orders. Upon the termination of the event of Force Majeure, **ETHYPHARM** shall be required to reinstate this Agreement.

CLAUSE 11 - TRANSFER PRICE OF THE PRODUCTS FROM BELMAC TO ETHYPHARM

BELMAC shall invoice **ETHYPHARM** for all supplies of Products and services in relation with the supply or the delivery of the Products at the following prices. These prices have been agreed for year 2001 and may be modified by mutual agreement between the Parties :

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1. SERVICES

- Encapsulation : 600 pesetas per 1000 doses
- Exportation service fees : 300 pesetas per 1000 doses
- Filling in packs : 100 ptas per pack of 14 capsules

2. MANUFACTURING COSTS

- Fixed Manufacturing costs (two production shifts and two GS machines) :
4 073.333 pesetas per month (price agreed upon for a period of 12 months)
- Fixed Week-end manufacturing costs (two shifts): 325 000 ptas
- Other manufacturing costs (processing costs only, excluding active ingredient
-non active ingredient (excipients) supplied by BELMAC) :
 - Omeprazol : 1.791 668 ptas for a batch of 1 250 000 doses (a dose
being the content of one capsule)
 - Piroxicam : 822 381 ptas for a batch of 2.000.000 doses
 - Vincamine : 416 000 ptas for a batch of 1.000.000 doses
 - Aspirine : 476 271 ptas for a batch of 1.700.000 doses
 - Indomethacin : 631 501 ptas for a batch of 1 500 000 doses
 - Lanzoprazol : 1315 107 ptas for a batch of 850 000 doses

Active ingredients needed to manufacture the Products are purchased directly by ETHYPHARM and delivered by ETHYPHARM to BELMAC prior to the beginning of production as mentioned hereinabove. BELMAC may not, in order to secure the quality and the supply prices, purchase directly active ingredient needed for the Omeprazol Product.

Inactive ingredients needed to manufacture the Products will be purchased directly by BELMAC. Said inactive ingredients will comply with the specifications indicated by ETHYPHARM and the registration dossiers of the Products. In order to guarantee the pharmaceutical and regular quality and supply of neutral pellets used for the Products BELMAC undertakes to purchase said neutral pellets exclusively from a supplier designated by ETHYPHARM.

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Payments shall be made by ETHYPHARM to BELMAC at 90 days end of the month the 10th date of invoice.

3. PRODUCTION WASTE FACTOR

BELMAC will be responsible for yield losses and waste in active ingredients, during the manufacturing of the Products, in excess of standard, calculated annually. Standard yield and waste mutually agreed upon by the Parties for each batch of the Products is fixed at 95 % (ninety five per cent) of the quantity processed.

BELMAC's liability for batch failures or excess yield losses in any contract year for reasons attributable to BELMAC shall be the cost of the active ingredients supplied by ETHYPHARM with appropriate documentation. ETHYPHARM shall have no obligation to BELMAC for any of BELMAC's costs associated with, or for the purchase price of, any batch failure for reasons attributable to BELMAC.

CLAUSE 12 -- TRANSFER PRICE OF OMEPRAZOL PRODUCT FROM ETHYPHARM TO BELMAC

Part of the production made by BELMAC under this Agreement with respect to the Product Omeprazol is bound to cover BELMAC and its Licensees needs.

As a consequence, ETHYPHARM shall invoice BELMAC for the quantity of Omeprazol Product manufactured by BELMAC under this Agreement at the price mentioned below

The supply price of the Product Omeprazol agreed upon between the Parties for year 2001 is the following :

- Omeprazol : 29 500 ptas per Kg of microgranules dosed at 85,5 mg/g of Omeprazol.

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This price includes active ingredient Omeprazol and is subject to review between the Parties on a quarterly basis.

Payments shall be made by BELMAC to ETHYPHARM at 90 days end of the month the 10th date of invoice.

This price shall also apply in the event of termination of this Agreement and in the event of manufacture by ETHYPHARM for reasons of Force Majeure.

CLAUSE 13 - BACK UP PRODUCTION BY ETHYPHARM

In the event, production capacity of BELMAC, as agreed upon in this Agreement, is not sufficient to manufacture all quantities of the Product Omeprazol for BELMAC's needs and the needs of its Licensees, ETHYPHARM will organize for BELMAC to be supplied from one of ETHYPHARM's production sites for the missing quantities. Conditions of supplies from ETHYPHARM to BELMAC will be identical to those agreed upon in clause 12 herein-above.

CLAUSE 14 - EXCLUSIVITY

ETHYPHARM warrants that it will not manufacture the Products in any other factory in Spain as long as the present Agreement remains in force and except for, for example, any of the following reasons :

- 1) BELMAC commits a material breach of its obligations.
- 2) The quality of the services rendered by BELMAC are not up to the standard normally expected for such services as noted during audits performed either by ETHYPHARM, Customers, Licensees or the competent Health Authorities of the Territory,
- 3) The manufacturing and control of the Products are not performed anymore in accordance with cGMP's.

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- 4) Authorizations to BELMAC to act as pharmaceutical laboratory are withdrawn or not renewed by the competent authorities.
- 5) In case of total or partial destruction of the Premises.

The foregoing terms do not prevent ETHYPHARM from producing the Products in one of its French production facilities for its Customers and ETHYPHARM's facility shall be also used as back-up production site for the Omeprazol Product sold by BELMAC and its Licensees.

CLAUSE 15 - NON COMPETITION

BELMAC warrants that during the validity of the present Agreement and for an additional period of five (5) years after its termination

- 1) BELMAC will not either directly or indirectly work or develop products identical or similar to ETHYPHARM's Products.
- 2) BELMAC's personnel trained by ETHYPHARM or having access to confidential information on ETHYPHARM's Products will be sued as breaching the obligation of confidentiality of clause 13 hereinafter if working on products identical or similar to ETHYPHARM's Products for BELMAC or for any third parties.
- 3) BELMAC will not put at the disposal of third parties involved in the exploitation of medicines, during the term of this Agreement only, any and all parts of the premises used for ETHYPHARM's Products and BELMAC will not purchase any equipment in order to produce any products which are similar or competing with the Products of ETHYPHARM or to use part or all of the Technology, ETHYPHARM's Know How and/or ETHYPHARM's patent rights to manufacture the Products, competing thus with ETHYPHARM and/or its Customers.

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CLAUSE 16 -CONFIDENTIALITY

All the information transmitted by **ETHYPHARM** to **BELMAC** pursuant to this Agreement will be considered strictly confidential and will not be divulged by **BELMAC** to third parties without the prior written agreement of **ETHYPHARM**. Affiliates, Licensees, and overseas agents of **BELMAC** are considered as third parties.

BELMAC may not use the confidential information received from **ETHYPHARM** otherwise than as provided for in this Agreement and particularly to manufacture the Products for itself or its Licensees without the prior written agreement of **ETHYPHARM**.

In the event of termination of this Agreement, all confidential data (among which but not limited to all data relative to the manufacturing processes, quality and analytical procedures of **ETHYPHARM**'s Product) transmitted by **ETHYPHARM** to **BELMAC** will be returned to **ETHYPHARM** within thirty (30) days after receiving the termination notice and **BELMAC** may not use them anymore.

This obligation of Confidentiality shall continue in effect for ten (10) years beyond the expiry of this Agreement for any reason.

Nevertheless, this obligation shall not apply where :

- the Information can be shown by **BELMAC** to have been in the public domain at the time it was received from **ETHYPHARM**,
- the Information, having been transferred, subsequently comes into the public domain other than by way of **BELMAC** or its employees,
- **BELMAC** can show that the information was already in its possession at the time it was transferred by **ETHYPHARM**, provided that it had not been obtained directly or indirectly from **ETHYPHARM** under a contract of secrecy still in force,

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- BELMAC has received the Information from a third party without any obligation to secrecy, provided that this third party did not obtain the Information directly or indirectly under a contract of secrecy still in force.

CLAUSE 17 - INTELLECTUAL PROPERTY

BELMAC represents that ETHYPHARM is the owner of all intellectual property rights related to the Technology and the Products. BELMAC shall not by virtue of this Agreement acquire any property right or title in ETHYPHARM's Technology and the Products and shall not, except as authorised hereunder, make any use thereof without the prior written consent of ETHYPHARM.

ETHYPHARM recognizes that BELMAC owns certain intellectual property relative to additional work performed by BELMAC and included in the Registration Files. Such intellectual property does not concern the Technology and Know How needed to manufacture and control the Products subject to the present Agreement.

In the event that BELMAC, at any time during this Agreement, shall become aware of any claim that the Technology infringes any intellectual property right of third parties in the Territory, it shall forthwith give promptly notice to ETHYPHARM. Following such notification, ETHYPHARM shall have full authority to decide what action to take in relation to such infringement.

CLAUSE 18 - ARBITRATION

If there is any controversy, claim or dispute arising out of this Agreement or the transactions contemplated by this Agreement, or any breach, alleged breach or anticipated breach of any of the foregoing (referred to here as a "Claim"), BELMAC and ETHYPHARM shall in good faith promptly meet and negotiate in an attempt to resolve that Claim. In the event that those negotiations do not resolve the Claim, all Claims arising from the Agreement will be definitively resolved by means of arbitration in law by one arbitrator, under the auspices of the spanish arbitration court, in accordance with its regulations and by-laws, to which the conduct of the arbitration

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and the appointment of the arbitrator is entrusted. The parties set forth their agreement to honour any award rendered.

CLAUSE 19 - GOVERNING LAW

The Agreement shall be interpreted and construed in accordance with the provisions of Spanish law.

CLAUSE 20 -NOTICES

The notifications or communications derived from this Agreement should be sent to the following addresses and fax numbers :

a) For BELMAC :

address :

attention :

fax number

b) For ETHYPHARM :

address : ETHYPHARM S.A.

Marques de la Ensenada, 16

28 MADRID – Espagne

attention : Mr Patrice DEBREGEAS

fax number :

With copy to :

ETHYPHARM S.A.

194 Bureaux de la Colline

Batiment D

92213 SAINT CLOUD – France

Attention : Mr Gérard LEDUC – General Manager

Mr Patrice DEBREGEAS – President

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Fax number : 00 33 1 41 12 17 30

Any modification to the above mentioned addresses, contact person or fax numbers may only be made by means of an Addendum to the present Agreement.

CLAUSE 21 - LANGUAGE

This Agreement shall be executed and effective in English language. Translation into Spanish may be needed for working purposes but in the event of a dispute as to the interpretation of the Agreement, the English version shall prevail.

CLAUSE 22 - ASSIGNMENT

BELMAC may not assign its rights or obligations arising from this Agreement without the prior written consent of ETHYPHARM.

CLAUSE 23 - INDEPENDENT CONTRACTOR

BELMAC is and shall always remain an independent contractor in its performance of this Agreement. The provisions of this Agreement shall not be construed as authorizing or reserving to ETHYPHARM any right to exercise any control or direction over the operations, activities, employees or agents of BELMAC in connection with this Agreement, it being understood and agreed that the entire control and direction of such operations, activities, employees, or agents shall remain with BELMAC as an independent contractor.

Neither party to this Agreement shall have any authority to employ any person as an employee or agent for or on behalf of the other party to this Agreement for any purpose, and neither party to this Agreement, nor any person performing any duties or engaging in any work at the request of such party, shall be deemed to be an employee or agent of the other party to this Agreement.

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CLAUSE 24 ENTIRE AGREEMENT

This Agreement constitutes the entire understanding between the parties, a complete allocation of risks between them and a complete and exclusive statement of the terms and conditions of their agreement; and all prior agreements, negotiations, dealings and understandings, whether written or oral, regarding the subject matter hereof, if contradictory with the terms of this Agreement, are hereby superseded and merged into this Agreement except as otherwise provided herein.

Each party acknowledges that there are no other understandings which relate to the matters covered herein or are inconsistent with any provisions of this Agreement.

CLAUSE 25 AMENDMENTS AND WAIVER

This Agreement cannot be amended in any respect except in writing duly executed by both parties. No waiver of compliance with any provisions or conditions of this Agreement and no approvals provided for in this Agreement shall be effective unless evidenced by a written instrument executed by the party to be charged.

No modification shall be effected by the acknowledgment or acceptance of purchase order or shipping instruction forms containing terms or conditions at variance with or in addition to those set forth in this Agreement.

CLAUSE 26 - MISCELLANEOUS

As used in this Agreement, employees or agents of a party hereto shall be deemed to include such party's past, present and future officers and directors.

Section headings as to the contents of particular sections are for convenience only and are in no way to be construed as part of this Agreement or as a limitation of the scope of the particular sections to which they refer.

If any term or provision of this Agreement or any application thereof shall be invalid or unenforceable, the remainder of this Agreement or any other application of such term or provision shall not be affected thereby.

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CLAUSE 27 - COSTS AND FEES

All taxes and expenses derived from the execution of the Agreement, including V.A.T. will be supported by the parties according to law.

Signed at Madrid

Date :

For **ETHYPHARM S.A.**

Mr Patrice DEBREGEAS

President

For **BELMAC S.A.**

Mr James R. MURPHY

Executive Director

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ANNEX A TO THE AGREEMENT
BETWEEN BELMAC S.A. AND ETHYPHARM S.A. (SPAIN)

PRODUCTS

OMEPRAZOL : sustained release organic formulation of Omeprazol in the form of microgranules in the 10 mg and 20 mg dosage forms subject to European Patent n° EP 646006 based on French priority FR9207249 applied for on June 16, 1992 and issued in Europe on March, 3, 1997 in the name of **ETHYPHARM S.A.** (Spain) .

PIROXICAM in the form of microgranules in the 20 mg dosage forms

VINCAMINE in the form of microgranules in the 30 mg dosage forms

ASPIRINE in the form of microgranules in the 150-300 mg dosage forms

INDOMETHACIN in the form of microgranules in the 50 mg dosage forms

LANZOPRAZOL in the form of microgranules in the 15 and 30 mg dosage forms

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ANNEX B TO THE AGREEMENT

BETWEEN BELMAC S.A. AND ETHYPHARM S.A. (SPAIN)

**DETAILS OF PRIOR AGREEMENTS SIGNED BETWEEN ETHYPHARM
and BELMAC**

- 1) Certificate of BELMAC dated March 2nd, 1998 relative to the manufacturing of Omeprazol Product and ownership of technology, manufacturing methods and machinery
- 2) Agreement relative to the exclusive purchase of Omeprazol Product to ETHYPHARM (March 23, 2000).
- 2) Confidentiality agreement signed by BELMAC's personnel in February 1996
-Mr Mateo Gasca Guillen
Mr Antonio Cabodevilla Ilincheta
Mr Juan Carlos Asensio Asensio
Mr Clemente Gonzalez Azpeita
Mr Jos  Luis Monterde Maorad
- 3) Confidentiality Agreement relative to Omeprazol 20 mg -- technical documentation (february 8, 1995)
- 4) Confidentiality Agreement relative to information contained in the registration file of Belmazol (September 30, 1998)
- 6) Manufacturing Agreements dated March 13, 2000 for each of Piroxicam, Vincamine, Indomethacin, Aspirine
- 7) Manufacturing Agreement dated March 23, 2000 for Omeprazol 20 mg.
- 8) Letter of November 6, 1992 relative to the cooperation between the parties and listing equipments pertaining to ETHYPHARM.

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INVESTMENT MADE BY ETHYPHARM (as per Whereas 2)

1) Investment

2) Equipment :

6 classical pans

2 GS Pellegrini pans

1 GS Pellegrini pan (rented by ETHYPHARM to a third party)

List of additional equipment attached to this Agreement.

3) Documentation transmitted to BELMAC.

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